IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	)	Case No. 24-md-03094-GEKP

PLAINTIFFS' POSITION STATEMENT

I. Introduction

This Statement is submitted on behalf of Plaintiffs to outline for the Court their position on the Defendants' glucagon-like peptide-1 receptor agonists ("GLP1-RA") drug labels, the common injuries alleged to be caused by those drugs, and to provide a brief overview of the unprecedented marketing funded by the Defendants. It is Plaintiffs' position that the aggressive marketing conduct described herein has altered the landscape for weight loss and diabetes treatment in this country without responsible disclosure of the severe injuries that these drugs can cause while omitting significant limitations on the benefits of these drugs. This Statement also summarizes the legal claims and issues that are expected to be central to this MDL.

II. The GLP1-RA Drugs and Their Labeling

A. Victoza and Saxenda (liraglutide)

In January 2010, Novo first launched Victoza as a once daily injectable as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.[1] In July 2023, Novo added

[1] *See Victoza Label* FOOD & DRUG ADMINISTRATION (revised 1/2010), https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022341lbl.pdf (last visited Apr. 9, 2024).

ileus to the 'Postmarketing Experience' of the Victoza label.[2] The Victoza label has never warned of gastroparesis or intestinal blockage as a potential consequence of use. While not in the Warnings section, under the "Use in Specific Populations" section of the Victoza label, Novo states, "Victoza slows gastric emptying. Victoza has not been studied in patients with pre-existing gastroparesis."[3] Other than counseling against use in patients with pre-existing gastroparesis, this statement provides no Warning that gastroparesis is a potential consequence of use.

In December 2014, Novo launched daily injectable Saxenda[4] as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in obese adults and in overweight adults with at least one weight-related comorbid condition. On April 20, 2023, Novo added ileus to the 'Post-Marketing Experience' section of Saxenda's label.[5] The label for Saxenda does not mention and has never warned that gastroparesis or intestinal obstruction is a potential consequence of use. Under the "for Use in Specific Populations" section in the Saxenda label (not the "Warnings" section), Novo states "SAXENDA slows gastric emptying. SAXENDA has not been studied in patients with pre-existing gastroparesis" and counsels against use in individuals who have gastroparesis. Besides this statement regarding pre-existing gastroparesis, the Saxenda label bears no Warning that gastroparesis is a risk despite its occurrence in thousands of users.

B. Trulicity (dulaglutide)

In September 2014, Lilly launched injectable Trulicity as an adjunct to diet and exercise to improve glycemic control in individuals with type 2 diabetes. Trulicity's label has never warned

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[2] *See Victoza Label* FOOD & DRUG ADMINISTRATION (revised 7/2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022341s039lbl.pdf (last visited Apr. 9, 2024).
[3] *See Victoza Label* FOOD & DRUG ADMINISTRATION (revised 1/2010), https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022341lbl.pdf (last visited Apr. 9, 2024).
[4] *Saxenda Label*, FOOD & DRUG ADMINISTRATION (revised Apr. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/206321s016lbl.pdf (last visited Mar. 29, 2024).
[5] *FDA Approval Letter for NDA 206321/S-016*, FOOD & DRUG ADMINISTRATION (Apr. 20, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/206321Orig1s016ltr.pdf.

of the risks of gastroparesis or intestinal obstruction, and ileus was only added to the "Postmarketing Experience" section (not the Warnings section) of the label in November 2022.[6]

C. Ozempic, Rybelsus, and Wegovy (semaglutide)

The labels for Ozempic, Rybelsus, and Wegovy have never warned of the risks of gastroparesis or intestinal obstruction. In December 2017, Novo launched Ozempic (semaglutide) as a once weekly injectable and as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.[7] On September 22, 2023, Novo added "Gastrointestinal: ileus" to the Postmarketing Experience section of Ozempic's label,[8] but the label still bears no Warning for either gastroparesis or ileus. Mentioning that an event has happened, without context or a statement that it is a risk presented by use of the drug, does not adequately warn physicians or patients.

In the fall of 2019, Novo launched *oral* Rybelsus (semaglutide), also as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.[9] On January 12, 2023, Novo added "Gastrointestinal: ileus" to the label's Postmarketing Experience section.[10]

Two years later in June 2021, Novo launched Wegovy (semaglutide) injections for chronic weight management in obese adults and in overweight adults with at least one weight-related comorbid condition. In December 2022, ileus was added to the Postmarketing Experience section

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[6] *See Trulicity Label*, FOOD & DRUG ADMINISTRATION (revised Nov. 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125469s051lbl.pdf (last visited Mar. 29, 2024).

[7] *See Ozempic Label*, FOOD & DRUG ADMINISTRATION (revised Sept. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf (last visited Mar. 29, 2024).

[8] *FDA Approval Letter for NDA 209637/S-020 and NDA 209637/S-021*, FOOD & DRUG ADMINISTRATION (Sept. 22, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/209637Orig1s020,s021ltr.pdf (last visited Apr. 2, 2024); *Ozempic Label*, FOOD & DRUG ADMINISTRATION (revised Sept. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf (last visited Apr. 2, 2024).

[9] *FDA Approval Letter for Rybelsus*, FOOD & DRUG ADMINISTRATION (Sept. 20, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/213051Orig1s000ltr.pdf (last visited Apr. 2, 2024).

[10] *FDA Approval Letter for NDA 213051/S-012*, FOOD & DRUG ADMINISTRATION (Jan. 12, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/213051Orig1s012ltr.pdf (last visited Apr. 2, 2024).

of Wegovy's label.[11] In sum, the Novo GLP1-RA labels omit a Warning for the risks of gastroparesis and ileus.

D. Mounjaro and Zepbound (tirzepatide)[12]

In May 2022, Eli Lilly launched Mounjaro (tirzepatide)—a once weekly injectable tirzepatide as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. On July 28, 2023, Lilly revised Mounjaro's label to include mention of ileus in the Postmarketing Experience section of the label.[13]

In November 2023, Lilly was cleared to begin marketing tirzepatide under the brand name Zepbound, for chronic weight management for obese adults and overweight adults with at least one weight-related comorbidity.[14] The label for Zepbound mentions ileus in the Postmarketing Experience section of the label.[15] But neither the Mounjaro label nor the Zepbound label warns of the risk of gastroparesis, ileus or intestinal obstruction as potential consequences of use.

For Lilly's drugs Trulicity, Mounjaro, and Zepbound, the labels warned since launch that use of these drugs "may be associated with gastrointestinal adverse reactions, sometimes severe."[16] The label, however, specifically points to the Adverse Reactions section for a description of what these gastrointestinal reactions are, and there is no reference for gastroparesis or ileus. The label

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[11] *Wegovy Label*, FOOD & DRUG ADMINISTRATION (revised Dec. 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215256s005lbl.pdf (last visited Apr. 2, 2024).

[12] It is expected that cases involving Zepbound will be filed in the future.

[13] *Mounjaro Label*, FOOD & DRUG ADMINISTRATION(revised July 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf (last visited Apr. 2, 2024).

[14] *See FDA Approval Letter for Zepbound*, FOOD & DRUG ADMINISTRATION (Nov. 8, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/217806Orig1s000ltr.pdf (last visited Apr. 2, 2024).

[15] *Zepbound Label*, FOOD & DRUG ADMINISTRATION (revised Nov. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf (last visited Apr. 2, 2024).

[16] *Trulicity Label*, FOOD & DRUG ADMINISTRATION (revised 9/2014), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000Lbl.pdf (last visited Apr. 8, 2024); *Mounjaro Label*, FOOD & DRUG ADMINISTRATION (revised 5/2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf (last visited Apr. 8, 2024); and *Zepbound Label*, FOOD & DRUG ADMINISTRATION (revised 11/2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf (last visited Apr. 8, 2024)

for Trulicity states that the most frequent gastrointestinal adverse reactions were constipation, flatulence, abdominal distension, gastroesophageal reflux disease, and eructation. The Mounjaro and Zepbound labels bear a similar limited listing of less-serious gastrointestinal adverse events. In sum, the less-serious gastrointestinal reactions warned of in these GLP-1 RA labels were far different from the type of serious adverse events plaintiffs in this MDL are alleging, as discussed above. The labels further water down the gastrointestinal warning by stating that the drugs have "not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients."[17] As discussed above, this language does not adequately warn of any risk of developing gastroparesis due to the use of GLP-1 RAs.

The patient Medication Guide for Trulicity listing of "severe stomach problems" under possible side effects does not ameliorate the problems in the label.[18] A doctor's response to patient inquiries about the meaning of that language would necessarily be informed by the label. Without a Warning, the true severity and magnitude of the risk would most likely go undisclosed. Moreover, the guide adds to the confusion with the statement: "Other medicines like Trulicity may cause severe stomach problems. It is not known if Trulicity causes or worsens stomach problems."[19] Suggesting that similar drugs may cause severe stomach problems only serves to suggest that Trulicity does not.

The Mounjaro and Zepbound labels (in 2022 and 2023 respectively) and Medication Guide suffer from the same deficiencies. The Medication Guide states "stomach problems, sometimes severe, have been reported" in people who use these drugs – but as discussed above, notification

[17] *Id.*
[18] *Trulicity Label*, FOOD & DRUG ADMINISTRATION (revised 9/2014), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/125469Orig1s000Lbl.pdf (last visited Apr. 8, 2024).
[19] *Id*.

of occurrence of an injury, without context or risk information, is not an adequate warning.[20] Together, Plaintiffs refer to Trulicity, Saxenda, Ozempic, Wegovy, Rybelsus, Mounjaro and Zepbound as the GLP-1 RAs.

III. GLP1-RAs and Injuries

Synthetic GLP-1 RAs work by binding to the GLP-1 receptor, stimulating insulin production and slowing gastric emptying.[21] GLP-1 RAs also affect the central and peripheral nervous systems, through direct activation of the hypothalamus and hindbrain, or indirect activation through the vagus nerve.[22] GLP-1 RAs[23] can cause[24] serious and long-term injuries, including gastroparesis, bowel obstruction (referred to as ileus or intestinal blockage), pulmonary aspiration, deep vein thrombosis, and gallbladder disease. Currently, there are over eleven thousand FDA adverse event reports filed by the public for these conditions following use of Defendants' products.

The injuries alleged in this MDL cover a wide spectrum in terms of severity: Some plaintiffs see their symptoms resolve after a brief hospitalization and treatment including drugs or surgery; other plaintiffs develop grave and irreversible, secondary conditions, including

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[20] *Mounjaro Label*, FOOD & DRUG ADMINISTRATION (revised 5/2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215866s000lbl.pdf (last visited Apr. 8, 2024); *Zepbound Label*, FOOD & DRUG ADMINISTRATION (revised 11/2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217806s000lbl.pdf (last visited Apr. 8, 2024).

[21] Y Nakatani et al, *Effect of GLP-1 receptor agonist on gastrointestinal tract motility and residue rates as evaluated by capsule endoscopy*, DIABETES METAB (2017), https://pubmed.ncbi.nlm.nih.gov/28648835/ (Ozempic "Mechanism of Action" section states that "[t]he mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.").

[22] Gurdeep Singh et al. *Wegovy (semaglutide): a new weight loss drug for chronic weight management*, JOURNAL OF INVESTIGATIVE MEDICINE (2022), https://pubmed.ncbi.nlm.nih.gov/34706925/.

[23] The GLP-1 RAs manufactured by Defendants in this MDL include Ozempic, Wegovy, Saxenda, Victoza, and Rybelsus, manufactured by the Novo Nordisk defendants, and Trulicity, Mounjaro, and Zepbound, manufactured by Eli Lilly and Company.

[24] Mohit Sodhi et al., *Risk of Gastrointestinal Adverse Events Associated With Glucagon-Like Peptide-1 Receptor Agonists for Weight Loss*, JAMA (2023), https://jamanetwork.com/journals/jama/fullarticle/2810542 ("Use of GLP-1 agonists for weight loss compared with use of bupriorion-naltrexone was associated with increased risk of pancreatitis, gastroparesis, and bowel obstruction.").

malnutrition, dehydration, neurological disorders, and even death. Between these two extremes, there are many plaintiffs who continue to daily suffer from the effects of gastroparesis and bowel obstruction, despite treatment. Based on reports from our clients and review of the medical literature, plaintiffs anticipate that the most commonly alleged injuries will be gastroparesis or bowel obstruction. Accordingly, this section will focus on these injuries.

A. Most Common Injury Types

Gastroparesis is a weakening or paralysis of the stomach muscles, which slows or stops the movement of food from a person's stomach into their small intestine. Gastroparesis is sometimes referred to as delayed gastric emptying, or stomach paralysis.[25] The weak or paralyzed muscles around a GLP-1 RA user's stomach fail to grind up the food the GLP-1 RA user eats, and fail to push the food into the GLP1-RA user's small intestine at a healthy rate, such that the GLP-1 RA user's stomach takes too long to empty its contents.[26] Initial symptoms of gastroparesis include feelings of fullness immediately after starting a meal or long after eating a meal, nausea, vomiting, belching, heartburn, abdominal pain, and poor appetite.[27] Gastroparesis sufferers are at risk of dehydration due to repeated vomiting, malnutrition due to poor absorption of nutrients, difficulties controlling blood glucose, and bezoars (aggregates of inedible or undigested materials found in the gastrointestinal or "GI" tract).[28] Malnutrition and dehydration due to gastroparesis can cause additional injuries, both directly – due to the lack of nutrients and hydration – and indirectly – as with complications that can arise from repeated vomiting, or from the use of a

[25] *Definition and Facts for Gastroparesis*, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis/definition-facts.
[26] *Id.*
[27] *Symptoms & Causes of Gastroparesis*, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis/symptoms-causes#whatsymptoms.
[28] *Definition and Facts for Gastroparesis*, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES, https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis/definition-facts.

feeding tube. Although neither set of Defendants warn that their drugs can cause gastroparesis, as discussed in more detail below, Defendants acknowledge that their GLP-1 RAs work by causing a delay in gastric emptying.[29]

When food cannot flow through the intestines, this injury is referred to as "**bowel obstruction**" or "**intestinal blockage**." A bowel obstruction may be mechanical (i.e., physical matter blocking the intestine), or may be caused by a failure of the digestive muscles to advance food through the digestive system.[30] "**Ileus**" – also known as paralytic ileus or functional ileus – refers to intestinal blockage or bowel obstruction that occurs in the absence of a mechanical or physical blockage,[31] due to a failure of muscle contractions of the intestines.[32] As is the case with an acute mechanical obstruction of blockage of the intestines, serious and prolonged ileus will result in death if untreated. [33]

B. Injury Examples

Gastroparesis, intestinal blockage, and ileus injuries can range from moderate to severe, and from chronic to permanent – for example, filed plaintiffs suffering gastroparesis have alleged secondary effects that range from continuous and disabling stomach pain to malnutrition. Plaintiff Meredith Hotchkiss[34] used Lilly's Mounjaro and Trulicity before being diagnosed with gastroparesis. These GLP-1 RAs severely impaired Ms. Hotchkiss's ability to digest food,

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[29] *Ozempic Label*, FOOD & DRUG ADMINISTRATION (revised Sept. 2023), at 12.2, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209637s020s021lbl.pdf (last visited Mar. 29, 2024); *Mounjaro Label*, FOOD & DRUG ADMINISTRATION (revised July 2023), at 12.2, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215866Orig1s002s006lbl.pdf (last visited Apr. 2, 2024).
[30] David A. Smith et al., *Bowel Obstruction*, *STATPEARLS* (2024), https://pubmed.ncbi.nlm.nih.gov/28723004/.
[31] Elsworth C. Beach & Orlando De Jesus, *Ileus*, *STATPEARLS* (2024), https://pubmed.ncbi.nlm.nih.gov/32644363/.
[32] *Ileus*, MERCK MANUAL (Revised Apr. 2023), https://www.merckmanuals.com/home/digestive-disorders/gastrointestinal-emergencies/ileus.
[33] Elroy Patrick Weledji, *Perspectives on paralytic ileus*, ACUTE MEDICINE & SURGERY (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7533151/.
[34] Complaint, Nov. 21, 2023, *Hotchkiss v. Eli Lilly and Company*, No. 2:24-cv-00549-GEKP.

requiring doctors to put a feeding tube in place to ensure adequate nutrition. Ms. Hotchkiss has been hospitalized several times due to dehydration and feeding tube complications. For other plaintiffs, the unresolving symptoms of gastroparesis are debilitating. For example, Plaintiff Delisa Jones[35] took Ozempic for a few months before suffering severe vomiting and gastrointestinal burning, leading to gastroparesis. Ms. Jones requires medication to alleviate vomiting, and suffers from ongoing, severe stomach pain that has left her essentially bedridden.

The initial complaints likewise demonstrate a spectrum of bowel obstruction outcomes after use of the Defendants' GLP-1 RAs. Plaintiff Billie Farley,[36] age 47, took Ozempic for approximately four months before being diagnosed with multiple intestinal blockages, which required her to undergo eight hours of surgery, and be initially hospitalized for six days. Three days later, Ms. Farley returned to the hospital seeking treatment for severe abdominal pain but was advised that her abdominal pain would be permanent.

Gastroparesis and bowel obstruction can also occur comorbidly. Plaintiff Alesio Sciochetti,[37] age 58, began taking Ozempic in 2022. In October 2023, Mr. Sciochetti was taken to the emergency room with lower abdominal pain, nausea, and vomiting, where he was diagnosed with bowel obstruction, ileus, and gastroparesis. He was initially hospitalized for 13 days, during which time Mr. Sciochetti underwent an exploratory laparotomy and creation of enterotomy, and insertion of a left basilic vein 5 French dual-lumen peripherally inserted central catheter. Two days after being discharged from the hospital, Mr. Sciochetti returned to the emergency room with abdominal pain, nausea, sweats, and chills due to post-operative fluid collection/abscess, and was hospitalized for an additional three days.

[35] Complaint, Nov. 16, 2023, *Jones v. Novo Nordisk*, No. 2:24-cv-00550-GEKP.
[36] Complaint, Dec. 8, 2023, *Farley v. Novo Nordisk*, No. 2:23-cv-04866-GEKP (E.D. Pa.).
[37] Complaint, Jan. 10, 2024, *Sciocchetti v. Novo Nordisk*, No. 2:24-cv-00690-GEKP (E.D. Pa.).

IV. Novo Nordisk's and Eli Lilly's Marketing of the GLP1-RA Drugs

Novo Nordisk and Eli Lilly have marketed the GLP-1 RAs at issue in this case aggressively. In 2023, Novo Nordisk spent $263 million dollars advertising Wegovy and $208 million dollars advertising Ozempic.[38] In the same year, Lilly spent $139 million advertising Mounjaro, more than 16 times their spending in 2022.[39] According to open payments data, Novo Nordisk spent $33,927,336.42 on "marketing/consulting/travel/food" and beverage/etc" to physicians in 2022 alone.[40] Lilly has spent at least $3.5 million in physician meal payments promoting Mounjaro and Trulicity.[41] Novo Nordisk has paid at least $25.8 million over the past decade to U.S. medical professionals to promote sales of its two drugs approved specifically for obesity, Wegovy and Saxenda.[42] Novo Nordisk's presentation on capital markets day makes it clear that these campaigns are designed to "activate more people to seek treatment for obesity."[43]

Novo Nordisk's marketing strategy includes traditional pharmaceutical marketing in combination with a novel use of social media and online advertising campaigns. Traditional pharmaceutical marketing by Novo Nordisk includes physician detailing and payments, continuing

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[38] Annika Kim Constantino, *Healthy Returns: Weight loss, diabetes, drug ad spending tops $1 billion*, CNBC (Apr. 3, 2024), https://www.cnbc.com/2024/04/03/weight-loss-diabetes-drug-ad-spending-tops-1-billion.html.

[39] *Id*.

[40] *Novo Nordisk Inc.*, OPENPAYMENTSDATA (last visited Sept. 18, 2023), https://openpaymentsdata.cms.gov/company/100000000144.

[41] John LaMattina, *Fattening Doctors to Promote Weight Loss Drugs*, FORBES (Jul. 20, 2023), https://www.forbes.com/sites/johnlamattina/2023/07/20/fattening-doctors-to-promote-weight-loss-drugs/?sh=5684f5b9b1f1.

[42] Chad Terhune & Robin Respaut, *Maker of Wegovy, Ozempic showers money on U.S. obesity doctors*, REUTERS (Dec. 1, 2023), https://www.reuters.com/investigates/special-report/health-obesity-novonordisk-doctors/.

[43] Novo Nordisk, *Obesity care powerpoint*, (March 3, 2022) https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day-2022/P5-obesity-care.pdf (last visited on April 9, 2023).

medical education,[44] key opinion leaders,[45] funding advocacy groups,[46] lobbying groups,[47] celebrity endorsements,[48] coupon programs,[49] and unbranded[50] and branded[51] direct-to-consumer advertising on television and online.

Novo Nordisk has also expanded its marketing to two novel areas for a pharmaceutical manufacturer: direct partnerships with telehealth providers[52] and use of social media campaigns. Novo Nordisk's advertising on social media is unprecedented in pharmaceutical marketing.[53] This includes directly partnering with social media giant, Meta, to advertise their drugs on Instagram.[54] Novo Nordisk also owns and operates the website "It's Bigger Than Me."[55] This advertising website – one of many websites funded by Novo Nordisk – promotes the message that obesity is a chronic disease and patients need to seek medical care from their physician.[56] This campaign was described by Novo Nordisk as follows:

> "**It's Bigger Than Me** didn't just launch; it catapulted . . . the launch . . . generated a frenzy of positive, high message pull-through coverage with 147 broadcast airings, 146 unique stories, 143B potential impressions, and a complete organic

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[44] *FORWARD: Focus on Obesity Education*, SCIENTIFIC EXCHANGE, https://www.scientific-exchange.com/therapeutic-areas/obesity/forward.html (last visited April 6, 2024).
[45] Julie Hollar, *60 Minutes' weight-loss tip: Don't bite the hand that feeds you*, MR ONLINE (Feb. 12, 2023), https://mronline.org/2023/02/13/60-minutes-weight-loss-tip/.
[46] *Novo Nordisk Renews Support for OAC Chairman's council at Platinum Level*, OBESITY ACTION NETWORK (Apr. 1, 2023), https://www.obesityaction.org/novo-nordisk-renews-support-for-oac-chairmans-council-at-platinum-level/.
[47] Rachana Pradhan, *Ozempic and Wegovy maker courts prominent Black leaders to get Medicare's favor*, NPR (Aug. 7, 2023), https://www.npr.org/sections/health-shots/2023/08/07/1192279278/ozempic-and-wegovy-maker-courts-prominent-black-leaders-to-get-medicares-favor.
[48] *Id*.
[49] *Get Wegovy Savings and WeGo Together support*, NOVOCARE, https://www.novocare.com/obesity/products/wegovy/savings-offer.html (last visited April 6, 2024).
[50] *See, e.g.*, IT'S BIGGER THAN ME, https://www.itsbiggerthan.com/ (last visited April 6, 2024).
[51] *See, e.g.*, BELIEVE ON, https://www.believeon.com/ (last visited April 6, 2024).
[52] *See, e.g.*, Beth Snyder Bulik, *Novo Nordisk teams with trending weight loss app Noom to help obesity patients*, FIERCEPHARMA (OCT. 11, 2019), https://www.fiercepharma.com/marketing/novo-nordisk-teams-trending-weight-loss-app-noom-to-help-patients-obesity.
[53] *See* Ben Adams, *As Novo Nordisk boots Wegovy, Ozempic ad spend, analysis finds 'a rising tide lights all boats' for diabetes, weight-loss drugs*, FIERCEPHARMA (Sept. 29, 2024) https://www.fiercepharma.com/marketing/novo-nordisk-boosts-Wegovy-Ozempic-ad-spend-analysis-finds-rising-tide-lifts-all-boats.
[54] *Novo Nordisk*, INSTAGRAM, https://business.instagram.com/success/novo-nordisk (last visited Apr. 9, 2023).
[55] IT'S BIGGER THAN ME, https://www.itsbiggerthan.com/ (last visited April 6, 2024).
[56] *Novo Nordisk*, Youtube, https://youtu.be/M8Xb6v58h5U?si=3rHW81DQmOhYFFtJ (last visited Apr. 9, 2024).

> takeover of the Google news section. Our website saw a significant spike in traffic with over 315K sessions, 585K page views and a video completion rate of 59% on the campaign creative to date. Across social channels, our videos reached over 26M users, generating over 7M total engagements."[57]

The hashtag #itsbiggerthan also reveals paid social media influencers promoting "body positivity" to promote Novo Nordisk's website (and ultimately their GLP-1 RAs).[58] Because consumers are more likely to purchase something when recommended by a trusted peer, social media influencers are particularly powerful in promoting pharmaceutical drugs. Social media influencers often promote products with short videos that are embedded in a user's TikTok or Instagram feeds; this type of "native advertising" is extremely effective as consumers often do not realize they are even viewing an advertisement.[59]

More insidiously, this unbranded marketing campaign – and the multiple others like it that are funded by Novo Nordisk[60] – collects a significant amount of data about prospective patients or customers. This research is used to "understand the mindsets of the people [Novo Nordisk] is trying to reach" and target them with additional advertisements.[61]

This use of big data and social media is particularly relevant when half of GLP-1 RA prescriptions come from telehealth providers – many of which solely prescribe weight loss drugs.[62] Novo Nordisk has partnered directly with Noom, one such telehealth provider, in promoting its

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[57] *It's Bigger Than Me, Finalist*, SHORTY AWARDS, https://shortyawards.com/14th/its-bigger-than-me (last visited April 6, 2024).
[58] *See, e.g.*, Katie Sturino (@katiesturino), INSTAGRAM, https://www.instagram.com/reel/CeygO0ZDkVu/?igsh=MTZjdm1nbzQwYTRoaA== (last visited April 6, 2024).
[59] *Native Advertising: A Guide for Businesses*, FEDERAL TRADE COMMISSION, https://www.ftc.gov/business-guidance/resources/native-advertising-guide-businesses (last visited Apr. 6, 2024).
[60] *See, e.g*, *See, e.g*, RETHINK OBESITY, https://www.rethinkobesity.com/ (last visited Apr. 9, 2024); TRUTH ABOUT WEIGHT, https://www.truthaboutweight.com/ (last visited Apr. 9, 2024).
[61] *It's Bigger Than Me, Finalist*, SHORTY AWARDS, https://shortyawards.com/14th/its-bigger-than-me (last visited April 6, 2024).
[62] Katie Palmer, *Where are patients getting their prescriptions for GLP-1 drugs like Wegovy and Ozempic?*, STAT NEWS (Aug. 10, 2023), https://www.statnews.com/2023/08/10/wegovy-ozempic-weight-loss-telehealth-prescriptions/.

early weight loss drug Saxenda,[63] and the Novo Nordisk Foundation has continued to invest directly in Noom.[64] Lilly takes this one step further and now offers LillyDirect – a vertically integrated telehealth service that will provide weight loss drugs delivered via Amazon to patients.[65] Telehealth providers allow prospective patients to obtain prescription for weight loss medications within minutes, and without needing to leave their sofa. Many of these telehealth services provide misleading information about weight loss medication, as Novo Nordisk has publicly conceded.[66]

Novo Nordisk and Eli Lilly both promote Ozempic and Mounjaro for weight loss, despite those GLP-1 RAs not being FDA approved for that indication.[67] And both Defendants fail to disclose the true risks of their product to prospective patients, who are predominantly female.[68]

V. Theories of Liability (Legal Issues)

Plaintiffs have brought several types of claims under state law. Every Plaintiff in this MDL has alleged, under various states' law, that Defendants failed to adequately warn of conditions such as gastroparesis, ileus, intestinal or bowel obstruction, and associated secondary conditions, such as malnutrition. The labels for GLP-1 RAs have never adequately warned of the drugs' propensity to impair the ability to digest food or that relentless vomiting requiring hospitalization was a risk. No GLP-1 RA labels warn of the risk of gastroparesis, a paralysis of the stomach resulting in

[63] *Obesity Care*, NOVO NORDISK, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/pdfs/capital-markets-day/03-Obesity.pdf (last visited April 6, 2024).
[64] Laura Lovett, *Weight loss app Noom scores $540M in Series F funding*, MOBI HEALTH NEWS (May 25, 2021), https://www.mobihealthnews.com/news/weight-loss-app-noom-scores-540m-series-f-funding.
[65] Katie Gibson, *Eli Lilly teams with Amazon to offer home delivery of its Zepbound weight-loss drug*, CBS NEWS MONEYWATCH (Mar. 13, 2024), https://www.cbsnews.com/news/weight-loss-zepbound-eli-lilly-amazon/.
[66] *Social Media Ads Inject New Angle in Ozempic Cases*, LAW.COM (Mar. 15, 2024), https://www.law.com/2024/03/15/social-media-ads-inject-new-angle-in-ozempic-cases-its-going-to-be-a-huge-focus/?slreturn=20240306210335.
[67] Gina Kolata, *We Know Where New Weight Loss Drugs Came From, but Not Why They Work*, NYTIMES (Aug. 17, 2023), https://www.nytimes.com/2023/08/17/health/weight-loss-drugs-obesity-ozempic-wegovy.html.
[68] Erika Edwards, *As weight loss drugs soar in popularity, many who could benefit can't get them*, NBC NEWS (Feb. 2, 2023), https://www.nbcnews.com/health/health-news/ozempic-wegovy-weight-loss-drugs-demand-soars-rcna68425 (Novo Nordisk reporting 81% of Wegovy patients are female).

cessation of digestion. Rather, the labels downplay the severity of gastroparesis symptoms, and omit that they can be a feature of potentially life-threatening digestive impairment.[69]

Further, Defendants failed to advise prescribers and users of GLP-1RAs that, in order to maintain the benefits of the drugs, they will need to take them forever, that users will likely experience weight gain after drug cessation, that a large percentage of weight loss would be muscle loss, that the weight gain upon stopping the drugs would be fat and that this change in proportion of muscle to fat would leave patients metabolically *worse off than when they started the drugs*.

Plaintiffs expect that Defendants will pursue the affirmative defense of federal preemption, arguing that they are unable to change a label that has been approved by the FDA. However, Defendants can implement a unilateral label change through the changes being effected ("CBE") label change process. *See Merck v. Albrecht*, 139 S. Ct. 1668, 1673 (2019) (citing 21 C.F.R. § 314.70(c)(6)(iii)(A)). The defense of preemption of warnings claims is only available where defendants can demonstrate that they fully informed the FDA about the justification for the warning required by state law and that the FDA informed the manufacturer that it would not approve addition of the warning. *See Albrecht*, 139 S. Ct. at 1678; *see also id.* ("[M]eeting the standard we set forth would be difficult . . . ."); *Wyeth v. Levine*, 555 U.S. 555, 573 (2009) (preemption "is a demanding defense"). Thus, this defense will require discovery into the adequacy of Defendants' submissions to the FDA and any official agency action regarding the labels at issue.

Punitive damages will be sought in these cases. In the face of evidence from the clinical trials and post marketing adverse events, Defendants persisted in minimizing risks and engaging in unprecedented marketing, much of which was not only off label, but also intentionally masked as non-advertising. This conduct rose to the level of gross negligence, fraud or malice, with

[69] One MDL Plaintiff has brought a wrongful death claim, and more such claims are expected.

conscious disregard for the safety of Plaintiffs.

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Respectfully submitted,

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